

### **REMARKS/ARGUMENTS**

#### **Status of the claims:**

Upon entry of the present amendment, claims 1, 39 and 42 will be pending in the application and presented for examination. Claim 42 has been newly added. Claims 6, 11, 38, 40 and 41 are herein newly withdrawn without prejudice to further prosecution. Further consideration of the application is requested.

#### **Support for the amendments to the claims:**

Claim 1 has been amended to remove the phrase "a fatty acid monoglyceride". And to replace with the phrase "an active agent for preventing said viral infection". Support for this amendment is found in the Examples 1 and 2 of the application as filed. Claim 1 has also been amended to more specifically recite the claimed invention. In particular the prevention of HSV and HIV infections by octylglycerol containing liposomes. Support for the new limitations are found in claims 6 and 10 and Examples 1 and 2 of the application as originally filed.

Amendments to the dependent claim 39 are similar to those made to claim 1, i.e., the term "fatty acid monoglyceride" has been replaced by "active agent".

Support for the newly added claim 42 can be found in claim 39 as filed and the support of current claim 1.

#### **Rejections**

##### **1. First Rejection Under 35 U.S.C. §112, First Paragraph**

Claims 1, 6, 11 and 38-41 stand rejected as allegedly failing to comply with the written description requirement. In this regard, the Examiner has alleged that there is no support for the recital of "infectious agents having a lipid bilayer". Applicants point out that this phrase is no longer present in the pending claims. In fact, in the previously filed response, the cited term was amended. Hence, Applicants request the Examiner to withdraw this rejection.

**2. Second Rejection Under 35 U.S.C. §112, First Paragraph**

Claims 1, 6, 11 and 38-41 stand rejected as allegedly lacking enablement. In support of the rejection, the Examiner alleges that the specification is enabling for inhibition of HIV and HSV by octylglycerol containing liposomes (see page 6 of the office action). To further prosecution, claim 1 is amended without prejudice. As amended, claim 1 recites a method for preventing viral infections caused by HSV and HIV by administration to a subject octylglycerol-containing liposomes.

In view of the amendments to claim 1 Applicants submit that the claim 1 (the only independent claim) is fully enabled by the specification as originally filed. Accordingly, Applicants request the Examiner to withdraw the rejection.

**3. Rejection Under 35 U.S.C. §112, Second Paragraph**

Claims 1, 6, 11 and 38-41 are rejected as allegedly being indefinite. The Examiner points out that the compound of claim 1 is not a fatty acid monoglyceride. Applicants thank the Examiner for pointing out an obvious error; i.e., in the naming of an alkylglycerol compound. Accordingly, Applicants have replaced the term "fatty acid monoglyceride" with the term "an active agent for preventing said viral infection". In view of this amendment the Examiner's concern is rendered moot. Applicants, having overcome this rejection, request the Examiner to withdraw this rejection.

**4. Rejection Under 35 U.S.C. §102(b)**

Claims 1, 6, 11 and 38-41 are rejected as allegedly being anticipated by Isaacs (US Patent No. 5,466,714). The Examiner alleges that Isaacs discloses prophylaxis of enveloped viruses such as HIV, using fatty acid monoglycerides which include octylglycerol. Applicants point out that such an allegation does not form the basis for a proper 102(b) rejection. Clearly, claim 1 requires the use of octylglycerol-containing lipid vesicles. For the reference to qualify as prior art under 35 U.S.C. §102(b), the Examiner needs to address the anticipation of all the elements of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

*Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The Isaac's reference does not disclose octylglycerol-containing liposomes for the prevention of viral infections caused by HSV and HIV and, hence, the Icaacs reference does not qualify as prior art under 35 U.S.C. §102(b). In fact, the Icaacs reference does not teach the use of lipid vesicles. Accordingly, Applicants request the Examiner to withdraw the rejection.

#### **5. Rejection Under 35 U.S.C. §102(e)**

Claims 1, 6, 11 and 38-41 are rejected as allegedly being anticipated by Thormar (US Patent No. 6,596,763). The Examiner alleges that Thormar discloses fatty acid monoglycerides for the prevention and treatment of enveloped viruses. It is also alleged that the viruses include HIV and HSV and administration includes topical mode. Applicants point out that such an allegation does not form the basis for a proper 102(e) rejection. Clearly, claim 1 requires the use of octylglycerol-containing lipid vesicles. For the reference to qualify as prior art under 35 U.S.C. §102(e), the Examiner needs to address the anticipation of all the elements of the claim. The Thormar reference does not disclose octylglycerol-containing liposomes for the prevention of viral infections caused by HSV and HIV and, hence, the Thormar reference does not qualify as prior art under 35 U.S.C. §102(e). Clearly, the Thormar reference does not teach the use of lipid vesicles. Accordingly, Applicants request the Examiner to withdraw the rejection.

#### **6. Rejection Under 35 U.S.C. §103(a)**

Claims 1, 6, 11 and 38-41 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Eibl (US Publication no. 2002/0173489) in combination with Ho (US Publication no. 2004/0208921), Hostetler (US Publication no. 2001/0033862) and Firshein (U.S. Patent No. 6,121,245), individually or in combination. In this regard, the Examiner alleges that Eibl teaches formulations containing single chain lipids for infections such as HIV. The Examiner further alleges that Ho et al., Hostetler et al., and Firshein teach the use of liposomes as delivery agents for such drugs. To the extent that the rejection is applicable to the currently amended claim set, Applicants respectfully traverse the rejection.

**NO PRIMA FACIE CASE OF OBVIOUSNESS EXISTS**

Applicants respectfully point out that the currently amended claims are directed to methods of using liposomal formulations octylglycerols for the prevention of viral infections. In view of the amended claims, Applicants respectfully assert that a *prima facie* case of obviousness has not been established for the presently claimed invention. To establish a *prima facie* case of obviousness, three basic criteria must be met:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants respectfully submit that a *prima facie* case of obviousness has not been established because the cited references do not teach all of the claim limitations.

Eibl does not teach all the limitations of the only independent and currently amended claim 1. The differences are tabulated below.

Limitations of amended Claim 1	Eibl's teachings
<p>an active agent for preventing said viral infection is of formula:</p> $\begin{array}{l} \text{O}-\text{R}^1 \\   \\ \text{O}-\text{R}^2 \\   \\ \text{OH} \end{array}$ <p>wherein R<sup>1</sup> or R<sup>2</sup> is a octyl group and the other is hydrogen</p>	<p><i>These objects are achieved via a medicament which contains as active material at least one compound of the formula R-Y-P<sup>O</sup><sub>2</sub>-X-R<sub>I</sub> (see paragraph 11)</i></p> <p>It is not suggest in Eibl's reference that the active agent is an alkylglycerol. Alkylglycerol is used merely in combination with the above described active compound.</p>
a lipid vesicle	The Examiner notes that Eibl does not teach the use of a liposome.

a method for preventing a viral infection	<p>In the office action dated February 21, 2008, the Examiner notes that methods taught by Eibl are drawn to preventing proliferation and not preventing infection.</p> <p><i>Finally, since viruses such as HIV remain dormant and the antiviral agents actually prevent proliferation of the virus...</i></p>
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Firshein, while teaching that alkylglycerols can be administered in liposomal formulations, is drawn to methods for treating malignant tumors and not for preventing viral infections. This reference does not overcome all the deficiencies of Eibl's teachings.

Ho et al., as admitted by the Examiner, disclose liposomal formulations of drugs for targeted delivery to lymphoid tissues. However, Ho et al. do not teach the use of any alkylglycerol as an active agent for the prevention of viral infections. Hence, Ho et al. does not cure all the deficiencies of Eibl or Eibl in combination with Firshein.

Similarly, Hostetler et al. also fails to teach the use of an alkylglycerol for the prevention of viral infections. Hence, Hostetler et al. does not cure all the deficiencies of Eibl or Eibl in combination with Ho et al. and Firshein.

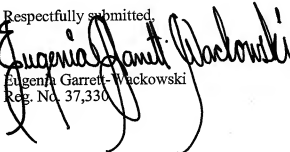
The combination of the cited references fails to teach or suggest all the claim limitations of the instant claims. As such, Applicants assert that no *prima facie* case of obviousness exists and respectfully request that this rejection be reconsidered and withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Eugene Garrett Wackowski". The signature is fluid and cursive, with the first name "Eugene" being the most prominent.

Eugene Garrett Wackowski  
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